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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/535,084 HARDER ET AL. Office Action Summary Examiner Art Unit BARBARA FRAZIER 1611 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 22 January 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-4 and 7-23 is/are pending in the application. 4a) Of the above claim(s) 1-3.8.10.11 and 16-23 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 4,7.9 and 12-15 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 4 and 7-18 in the reply filed on 1 1/22/08 is acknowledged. The traversal is on the ground(s) that Examiner has failed to establish that a serious burden would be placed on the Examiner if the restriction requirement was not made (MPEP 802.02). This is not found persuasive because the grounds upon which Applicants are basing their traversal (i.e., MPEP 802.02) apply to applications filed under 35 U.S.C. 111; the present application is a national stage entry of a PCT application, and is therefore filed under 35 U.S.C. 371. Accordingly, the restriction requirements for the present application are according to PCT Rules 13.1 and 13.2 (see MPEP 1850). As stated in the restriction requirement dated 12/20/07, the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature common to all of the groups cannot be considered a patentable advance over the art given that said feature, namely the formulation containing yttrium, neodymium, or zirconium, is old. For example, US Patent 4,610,241, cited in Applicant's International Search Report dated 8/3/04, discloses formulations containing yttrium useful in the treatment of atherosclerosis (see col. 1, lines 5-15 and col. 4, lines 17-34).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3 and 19-23 withdrawn from further consideration pursuant to 37 CFR
 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/22/08.

Applicant's election with traverse of the species of yttrium and an alloy as the carrier in 3. the reply filed on 1/22/08 is acknowledged. The traversal is on the ground(s) that the species identified by the Examiner are not mutually exclusive (MPEP 806.04(f)), citing the examples of 1) the claims in group II are "comprising" claims, 2) the overlap between the identified species a seen in claim 12, and 3) that the species of an alloy and a bioresorbable polymer are different embodiments of a biodegradable carrier, as recited in claim 4. This is not found persuasive because the grounds upon which Applicants are basing their traversal (i.e., MPEP 806.04(f)) apply to applications filed under 35 U.S.C. 111; the present application is a national stage entry of a PCT application, and is therefore filed under 35 U.S.C. 371. Accordingly, the restriction requirements for the present application are according to PCT Rules 13.1 and 13.2 (see MPEP 1850). As stated in the restriction requirement dated 12/20/07, the species listed [in the restriction requirement dated 12/20/07] do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The choices available for each of the elements and carriers for the formulations of claims 4 and 7-18 create combinations of formulations which vary significantly in structure and properties, so that the resulting formulations and/or methods of use would lack the same or corresponding special technical feature. For example, a formulation containing yttrium and an alloy would lack the same or corresponding technical feature as a formulation containing zirconium and a bioresorbable polymer.

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The requirement is still deemed proper and is therefore made FINAL.

- 4. Claims 8, 10, 11, and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/22/08.
- 5. Upon searching the prior art, it has been determined that the formulation containing a mixture of yttrium, neodymium, and zirconium is an obvious variant of the formulation containing yttrium alone; therefore, the examination has been extended to include formulations containing a mixture of yttrium, neodymium, and zirconium.
- Claims 4, 7, 9, and 12-15 are examined.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignces. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 425 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January I, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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8. Claims 4, 7, 9, 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 21-24 of copending Application No. 10/706,717. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter and composition components.

The claimed invention is drawn to a pharmaceutical formulation comprising yttrium (Y), neodymium (Nd), or zirconium for inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel and the formulation includes an at least very substantially biodegradable carrier (see claim 4).

The '717 application is drawn to an endoprosthesis comprising a carrier structure comprising a metallic material, which comprises a magnesium alloy of the following composition:

Magnesium: >90%

Yttrium: 3.7% - 5.5%

Rare earths: 1.5% - 4.4% and

Balance: <1%,

The "rare earths" may comprise neodymium (claim 4) and the "balance" may comprise zirconium (claim 5).

The '717 application differs from the claimed invention because it is named as an endoprosthesis, and because it does not recite the limitations of "pharmaceutical formulation" and "inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel".

However, the limitations in the claimed invention of are intended use and do not lend patentable weight to the composition as claimed. Furthermore, the intended use of the '717 application as "endoprosthesis" does not lend patentable weight to the composition as claimed. Therefore, the composition of the claimed invention and the '717 application are drawn to the same subject matter and composition components.

With respect to the dependent limitations of amounts of metals present, the '717 application teaches ranges which are encompassed by, or comparable to, the ranges taught in the claimed invention, and one skilled in the art would select optimal amounts of metals as a matter of routine experimentation.

With respect to the yttrium concentration in the region of the human smooth muscle cells to be treated (claim 15), the '717 application would be capable of adapting to provide such a concentration, especially given the fact that the amount of yttrium taught in the '717 application is encompassed by the amount of yttrium taught in the claimed invention. The limitation is one of intended use, and does not lend patentable weight to the composition as claimed.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 4, 7, 9, and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7-9, and 16-19 of copending Application No. 10/596,797. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter and composition components.

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The claimed invention is recited above (see paragraph 8).

The '797 application is drawn to a radiopaque marker for medical implants comprising 10 to 90 wt.% of a biodegradable base component, 10 to 90 wt.% of one or more radiopaque elements including Y and Nd, less than or equal to 10 wt.% residual components, the components cited adding up to 100 weight-percent. The biodegradable base component may be a magnesium alloy (claim 3). The definition of "residual components" in the '797 application includes Zr, and the definition of "magnesium alloy" includes WE43 (see paragraph 27, page 8).

The '797 application differs from the claimed invention because it recites the limitation of "radiopaque marker for medical implants", and it does not recite the limitations of "pharmaceutical formulation" and "inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel"

However, the limitations in the claimed invention are intended use and do not lend patentable weight to the composition as claimed. Furthermore, the intended use of the '797 application as "radiopaque marker for medical implants" does not lend patentable weight to the composition as claimed. Therefore, the composition of the claimed invention and the '797 application are drawn to the same subject matter and composition components.

With respect to the dependent limitations of amounts of metals present, the '797 application teaches ranges which are comparable to the ranges taught in the claimed invention, and one skilled in the art would select optimal amounts of metals as a matter of routine experimentation.

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With respect to the yttrium concentration in the region of the human smooth muscle cells to be treated (claim 15), the radiopaque marker of the '797 application would be capable of adapting to provide such a concentration, especially given the fact that the amount of yttrium taught in the '797 application is comparable to the amount of yttrium taught in the claimed invention. The limitation is one of intended use, and does not lend patentable weight to the composition as claimed.

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10. Claims 4, 7, 9, and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11 of copending Application No. 10/908,729. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter and composition components.

The claimed invention is recited above (see paragraph 8).

The '729 application is drawn to an implant for vessel ligature comprising an alloy which is at least partially biodegradable and which comprises:

greater than 87% magnesium:

from about 3% to about 6% yttrium;

from about 1% to about 5% lanthanide; and

a balance of about 0.0% to about 2%.

The "lanthanide" further comprises neodymium (claims 4 and 5), and the "balance" further comprises zirconium (claims 7-9 and 11).

The '729 application differs from the claimed invention because it recites the limitation of "implant for vessel ligature", and it does not recite the limitations of "pharmaceutical formulation" and "inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel".

However, the limitations in the claimed invention are intended use and do not lend patentable weight to the composition as claimed. Furthermore, the intended use of the '797 application as "implant for vessel ligature" does not lend patentable weight to the composition as claimed. Therefore, the composition of the claimed invention and the '729 application are drawn to the same subject matter and composition components.

With respect to the dependent limitations of amounts of metals present, the '729 application teaches ranges which are encompassed by or comparable to the ranges taught in the claimed invention, and one skilled in the art would select optimal amounts of metals as a matter of routine experimentation.

With respect to the yttrium concentration in the region of the human smooth muscle cells to be treated (claim 15), the implant of the '729 application would be capable of adapting to provide such a concentration, especially given the fact that the amount of yttrium taught in the '797 application is encompassed by or comparable to the amount of yttrium taught in the claimed invention. The limitation is one of intended use, and does not lend patentable weight to the composition as claimed.

 Claims 4, 7, 9, and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending

Balance

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Application No. 11/221,322 and claims 1-4 of copending Application No. 11/221,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter and composition components.

The claimed invention is recited above (see paragraph 8).

The '322 application and the '344 application are drawn to an endoprosthesis comprising a magnesium alloy of the following composition:

Magnesium: between about 60.0 and about 88.0% by weight Rare earth metals: between about 2.0 and about 30.0% by weight Yttrium: between about 2.0% and about 20.0% by weight Zirconium; between about 0.5% and about 5.0% by weight

The '322 application also comprises neodymium in claims 3 and 4; the '344 application also comprises neodymium in claim 1.

between 0 and about 10.0% by weight

The '322 application and the '344 application differ from the claimed invention because they recite the limitation of "endoprosthesis comprising a carrier structure", and they do not recite the limitations of "pharmaceutical formulation" and "inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel".

However, the limitations in the claimed invention are intended use and do not lend patentable weight to the composition as claimed. Additionally, the presence of a "carrier structure" in the '322 and '344 applications is not excluded from the pharmaceutical formulation of the claimed invention. Furthermore, the intended use of the '322 and '344 applications as

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"endoprosthesis" does not lend patentable weight to the composition as claimed. Therefore, the composition of the claimed invention and the '322 and '344 applications are drawn to the same subject matter and composition components.

With respect to the dependent limitations of amounts of metals present, the '322 and '344 applications teach ranges which are encompassed by or comparable to the ranges taught in the claimed invention, and one skilled in the art would select optimal amounts of metals as a matter of routine experimentation.

With respect to the yttrium concentration in the region of the human smooth muscle cells to be treated (claim 15), the endoprosthesis of the '322 application and the '344 application would be capable of adapting to provide such a concentration, especially given the fact that the amount of yttrium taught in the '322 and '344 applications is encompassed by or comparable to the amount of yttrium taught in the claimed invention. The limitation is one of intended use, and does not lend patentable weight to the composition as claimed.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 4, 7, 9, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Stroganov et al., US Patent 3,687,135.

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The claimed invention is drawn to a pharmaceutical formulation comprising one or more of the elements from the group yttrium (Y), neodymium (Nd), or zirconium (Zr) for inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel and the formulation includes an at least very substantially biodegradable carrier (see claim 4).

In the elected species of the claimed invention, the element is yttrium and the biodegradable carrier is a magnesium alloy.

Stroganov et al. teach a magnesium-base alloy for use in bone surgery which contains the following components, wt. % (see abstract):

Rare earth metal	0.404.0	
Cadmium	0.05-1.2	
Calcium or aluminum	0.051.0	
Manganese	0.05-1.0	
Silver	0-0.8	
Zirconium	0-0.8	
Silicon	0~0.3	
Magnesium	remainder	

Stroganov et al. further teach that neodymium and yttrium are predominantly employed as the rare earth metal (col. 2, lines 29-31). A magnesium alloy comprising yttrium at 1.6 wt.% is exemplified (see Example 3). The limitations in the claim of "inhibiting the proliferation of human smooth muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel" are not given patentable weight, since the composition of Stroganov et al. has pharmaceutical use in bone surgery, and thus would be capable of the intended use of the claimed invention. Therefore, the composition of Stroganov et al. anticipates the composition of the claimed invention.

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With respect to the yttrium concentration in the region of the human smooth muscle cells to be treated (claim 15), the composition of Stroganov et al. would be capable of adapting to provide such a concentration, especially given the fact that the amount of yttrium taught by Stroganov et al. is encompassed by the amount of yttrium taught in the claimed invention. The limitation is one of intended use, and does not lend patentable weight to the composition as claimed

With respect to the yttrium concentration in the region of human smooth muscle cells to be treated (claim 15), the composition of Stroganov et al. would be capable of performing the intended use of the claimed invention, especially given the fact that the amount of yttrium taught by Stroganov et al. is also taught by the claimed invention. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation; "adapted for" clauses are an example of such language (see MPEP 2106 II). Since the invention of Stroganov et al. and the invention as claimed are the same, the invention of Stroganov et al. would be capable of performing the intended use of providing an yttrium concentration in the region of the human smooth muscle cells to be treated of between 200 uM and 2 mM, in particular between 800 uM and 1 mM, as taught by claim 15.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35
- U.S.C. 103(a) are summarized as follows:
 - Determining the scope and contents of the prior art.
 - Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Stroganov et al., US Patent 3,687,135.

The claimed invention and the invention of Stroganov et al. are recited above (see paragraph 13).

With respect to claims 12-14, Stroganov et al. differ from the claimed invention because they do not exemplify a formulation comprising a magnesium alloy and containing Y, rare earths without Y, and remaining elements, or containing, Y, Nd, and Zr, in the weight percentages

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specified by the claims (the weight percentages for Y, Nd, and Zr in the biodegradable magnesium alloy WE43 are defined in Applicant's specification, page 15, paragraph 48).

However, Stroganov et al. do teach that the rare earth metals (i.e., Y plus rare earths without Y, or Y and Nd) in the range of 0.4-4.0 wt.%. Additionally, Stroganov et al. teach that zirconium may be present in amount ranging from 0-0.8 wt.%, and the total remaining elements may be present in amounts ranging from 0.15-5.1 wt.% (col. 2, lines 20-28). Stroganov et al. also teach that neodymium and yttrium are predominantly employed as the rare earth metal (col. 2, lines 29-31).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to form a pharmaceutical formulation having the elements and amounts as specified by the claimed invention with a reasonable expectation of success.

It is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. One skilled in the art would have been motivated to combine the elements of yttrium and neodymium as the rare earth metal in the composition of Stroganov et al., with a reasonable expectation of success. Additionally, one skilled in the art would have been motivated to select zirconium to be present in the formulation, since zirconium is already exemplified in the formulations of Stroganov et al. Furthermore, the amounts taught in Stroganov et al. are comparable to those taught in the claimed invention, such that one skilled in the art would be able to choose optimal amounts of elements as a matter of routine experimentation.

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One skilled in the art would have been motivated to combine the elements of yttrium and neodymium as the rare earth metal in the composition of Stroganov et al., with a reasonable expectation of success, because it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. Furthermore, the amounts taught in Stroganov et al. are comparable to those taught in the claimed invention, such that one skilled in the art would be able to choose optimal amounts of elements as a matter of routine experimentation.

Examiner's Remarks

In claim 14, regarding the term (W25/EP5M); the Examiner suggests deleting the term "(W25/EP/5M)" in order to improve the clarity of the claim. Additionally, the Examiner suggests adding the definition of the composition of WE43 as defined in page 15, paragraph 48 of the specification, in order to further improve the clarity of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/ Primary Examiner, Art Unit 1611